AUG 2 4 2004

K032291

Section 20 – 510(k) Summary

Submitted By:	Linde Medical Sensors AG Austrasse 25 4051 Basel – Switzerland Phone: 011 41 61 278 82 07 Fax: 011 41 61 278 81 81
Contact:	Jean-Pierre Palma Head of Mechanical Engineering/Regulatory Affairs
Date Summary Prepared:	July 18, 2003
Trade Name:	Tosca PCO_2, SpO_2 and Pulse Rate Monitoring System
Common/Classification Name:	Cutaneous Gas Monitor / Pulse Oximeter Monitor Carbon Dioxide Cutaneous (73LKD) / Oximeter (74DQA)
Substantially Equivalent Device:	MicroGas 7650 Transcutaneous Monitor (K003943) Kontron Pulse Oximeter 7840 (K890299)

Description of the Tosca PCO_2, SpO_2 and Pulse Rate Monitoring System

The Linde Tosca System is used for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (Tosca Sensor) applied to the ear lobe.

The system consist of a TOSCA Monitor equipped with an integrated calibration unit which allows a fully automatic calibration and also provides a storage facility for the sensor; a TOSCA Sensor comprising the elements of an electrochemical Stow-Severinghaus-type carbon dioxide sensor and of an optical pulse oximetry sensor; supplies for the sensor preparation; supplies for the sensor attachment at the ear lobe; and a gas mixture for the sensor calibration.

Intended Use

The Linde TOSCA system is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate in adults and pediatrics.

Principles of Operation

The Linde Tosca is used for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and pulse rate, using a single sensor (Tosca Sensor) applied to the ear lobe.

Transcutaneous measurement of PCO_2 makes use of the fact that carbon dioxide gas is able to diffuse through body tissue and skin and can be detected by a sensor at the skin surface. By warming up the sensor, a local hyperemia is induced, which increases the supply of arterial blood to the dermal capillary bed below the sensor. The PCO_2 portion of the Tosca sensor consists of a Stow-Severinghaus type electrode.

The principle of the SpO_2 measurement is based on the difference in the light absorption characteristics of haemoglobin in its oxygenated and reduced forms. The monitor calculates the percentage of oxygen saturation, i.e., the ratio of oxygenated haemoglobin to total haemoglobin. It does this by measuring the absorption of selected wavelengths of light passing through a sample of living tissue, for example an ear lobe.

Electrical, Mechanical and EMC Testing

Electrical, Mechanical and EMC Testing per IEC 60601 was performed and the Tosca Monitoring System passed all tests.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (24 hours to 30 days) as defined in ISO-10993-1:1992 Biological Evaluation of Medical Devices – part 1: Guidance on Selection of Tests. All patient contacting material passed.

Clinical Testing

The results of the clinical testing demonstrate that the Tosca PCO_2, $SpO_2$and Pulse Rate Monitoring System and accessories meet the performance requirements.

Conclusions

All test results demonstrate that the Tosca PCO_2, SpO_2 and Pulse Rate Monitoring System and accessories are safe, effective and performs as well as the predicated devices, the MicroGas 7650 Transcutaneous Monitor and the Kontron Pulse Oximeter 7840.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Mr. Jean-Pierre Palma
Head of Mechanical Engineering/Regulatory Affairs
Linde Medical Sensors AG
Austrasse 25
CH-4051 Basel
SWITZERLAND

Re: K032291
Trade/Device Name: TOSCA PCO_2, SpO_2 and Pulse Rate Monitoring System
Regulation Number: 870.2700, 868.2480
Regulation Name: Oximeter Cutaneous Carbon Dioxide ($PcCO_2$
Regulatory Class: II
Product Code: DOA, LKD
Dated: August 6, 2004
Received: August 9, 2004

Dear Mr. Palma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include equirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

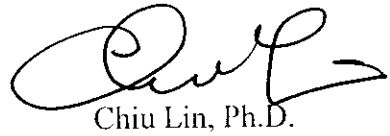
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K032291**

Device Name: **TOSCA PCO_2, SpO_2 and Pulse Rate Monitoring System**

Indications For Use:

The Linde TOSCA System is designed for the simultaneous continuous monitoring of transcutaneous PCO_2, functional oxygen saturation SpO_2 and Pulse Rate in adults and pediatrics.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K032291